

## 12/5/97 INTERNAL DISCUSSION DRAFT

December 15, 1997

BY HAND

Gregory N. Connolly, D.M.D., M.P.H.  
Director, Massachusetts Tobacco Control Program  
Massachusetts Department of Public Health  
250 Washington Street, Fourth Floor  
Boston, Massachusetts 02108

Re: 1997 Annual Report of Philip Morris Incorporated

Dear Dr. Connolly:

In accordance with Massachusetts General Laws, Chapter 94, Section 307B and the regulations promulgated by the Department of Public Health ("DPH") pursuant thereto, Philip Morris Incorporated ("Philip Morris") hereby submits the attached Section Two of its 1997 annual report to the DPH. In addition to this hard copy submission, Philip Morris submits the attached disc containing its submission in electronic form.

The comprehensive annual report comprises two sections, one identifying the constituents added to each cigarette brand style and generic cigarette manufactured by Philip Morris and distributed within the Commonwealth of Massachusetts. Section One is submitted together herewith, but under separate cover. Section One contains highly proprietary and competitively sensitive trade secret information for which Philip Morris requests confidential treatment.

This Section Two reports a variety of nicotine yield rating information for each cigarette brand style and generic cigarette manufactured by Philip Morris with a national market share in excess of five percent of the entire United States cigarette market and distributed within the Commonwealth of Massachusetts.

The Marlboro brand family of cigarettes, manufactured by Philip Morris, is the only Philip Morris brand family having a national market share greater than five percent as reported in the year-end 1996 and second-quarter 1997 Maxwell Reports published by [Davenport, as successor publisher of Maxwell

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7.  
 Reports to Wheat First Securities(?) and includes Marlboro brand styles currently distributed within the Commonwealth of Massachusetts. Therefore, pursuant to Sections 660.000 and 660.102 (A) and (B) of the Code of Massachusetts Regulations ("CMR"), Philip Morris provides the information included on Attachment A, in the form provided by the Commonwealth, with respect to all Marlboro brand styles manufactured by Philip Morris and currently distributed within the Commonwealth of Massachusetts.

### Nicotine Yield Rating Information

Please note the following with respect to the contents of Attachment A and Philip Morris' filing pursuant to Sections 660.000 and 660.103 (A) and (B) of the CMR.

Save for the most recent nicotine levels previously reported to the Federal Trade Commission ("FTC"), the data reported on Attachment A was generated by internal testing of Marlboro brand styles currently distributed within the Commonwealth of Massachusetts. With reference to the nicotine levels previously reported to the FTC, the nicotine levels for two Marlboro brand styles not collected by the Tobacco Institute Testing Laboratory ("TITL"), Marlboro Lights Menthol King Size Soft Pack and Marlboro Lights Menthol 100s Soft Pack, [confirm consistency of descriptors], were calculated and reported on the basis of Philip Morris' internal testing pursuant to the FTC's method. The two brand styles were not available in the marketplace at the time of the TITL collection of brand styles for which nicotine levels were most recently reported by the FTC.

The cigarettes tested for total nicotine content, percent filter ventilation, pH of cigarette smoke and "nicotine delivery under average smoking conditions" were collected through a market sampling conducted in accordance with Standard 8243 of the International Organization for Standardization ("ISO"). An equal number of samples was retained for internal testing by Philip Morris and previously delivered to your attention for the Commonwealth of Massachusetts.

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 77-210-1  
 With the exception of the FTC testing methods referenced above, all of the procedures designated for the testing of total nicotine content, ~~percent filter ventilation~~, pH of cigarette smoke and "nicotine delivery under average smoking conditions" are non-validated procedures which Philip Morris believes could be improved prior to or following submission of the 1998 Annual Report through a

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cigarette industry validation process. In accordance with the CMR recommendations, Philip Morris will participate in a cigarette industry validation process for each of the recommended procedures discussed below.

### Nicotine Measurement

In accordance with Section 660.102(B)(2) of the CMR, Philip Morris measured total nicotine content utilizing the Center for Disease Control's "Protocol for Analysis of Nicotine, Total Moisture and pH in Smokeless Tobacco Products" published in the Federal Register on May 2, 1997, Vol. 62, No.85, pp. 24115-6 (the "CDC Protocol"). Philip Morris has several concerns related to the application of the CDC Protocol to measure the nicotine content in cigarettes, rather than the six categories of commercially available smokeless tobacco products for which the methodology was developed.

With respect to the "Quality Control Pool" referenced at page 24117, Par. II. C. of the Federal Register, the CDC Protocol states that the "smokeless tobacco product should be enriched with nicotine at the high and low ends of expected values for the smokeless tobacco product." Philip Morris does not add nicotine to the cigarettes it manufactures and did not enrich the tobacco with nicotine as suggested by the method due to concerns with homogeneity (i.e. uniformity within the sample) and perceived safety concerns. As an alternative, Philip Morris selected two quality control pools of tobacco not yet manufactured into cigarettes containing blended tobacco, one quality control pool with a higher nicotine content than expected in the blended cigarette and one quality control pool with lower nicotine content than expected in the blended cigarette. The alternative was selected by Philip Morris in order to remain within the range of expected values for the cigarette tobacco. Philip Morris does not believe that the Quality Control Pool, with nicotine enrichment per the CDC Protocol, would have fallen within that expected range.

With reference to the calculations described in the CDC Protocol, several flaws were apparent to Philip Morris. The linear calibration equation referenced at page 24117, Par. II. D.8. of the Federal Register was found by Philip Morris to utilize an unreliable procedure due to the recommended recovery method. In addition, the nicotine standard and internal standards concentrations referenced at page 24117, Par. II. A and B of the Federal Register were both determined to be erroneous [need detail and more specific reference]. Finally,

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Section 660.102(B)(2) of the CMR and the CDC Protocol are inconsistent with respect to whether Philip Morris was to measure total nicotine content of the cigarette or total nicotine content per gram of tobacco. In accordance with Section 660.102(B)(2) of the CMR, Philip Morris measured total nicotine content of the cigarette. Philip Morris believes the procedures should be improved prior to submission of the 1998 Annual Report and that the procedure can be improved through a cigarette industry validation.

study

#### Filter Tip Ventilation Measurement

Philip Morris measured Percent Filter Tip Ventilation in accordance with Section 600.102(B)(3) of the CMR utilizing a model FDT100 Fidus Dilution Tester. As confirmed by the November 6, 1997 facsimile transmission Philip Morris received from Fidus Instrument Corporation ("Fidus"), a copy of which is included as Attachment B, ~~the Fidus model FDT100~~ utilized by Philip Morris in connection with the preparation of this submission is identical in functionality to the Filter Dilution (Ventilation) Testing Instrument (FDT) product no. FDT 232 required to be utilized by Section 600.102(B)(3) of the CMR.

*PDI/DDI manufactured by KC Automation*

*the instrument*

#### pH Measurement

Philip Morris could not determine the pH of the cigarette smoke in accordance with the method described with specificity in Section 660.102(B)(4) of the CMR, and Appendix 2D thereto, because the necessary equipment described in the referenced in the article by Hayes, et al, "A Method for Measuring the pH Value of Whole Smoke," (Tobacco Science, 1977:60:81-83) is not commercially available, nor is a functional equivalent.

Philip Morris is not aware of any standard or accepted method used by the cigarette industry or others to conduct smoke pH measurement. As detailed in Attachment C hereto, Philip Morris has developed and hereby submits a method of ~~measuring the pH of whole smoke of cigarettes (gas and particulate phases) using ISO templates~~. In addition, Philip Morris believes that the method described in Attachment C ~~for measuring the pH of whole smoke of cigarettes~~ should be reproducible across laboratories. Philip Morris will submit the procedure for validation once the procedures for validation contemplated by Section \_\_\_ of the CMR are established.

*Agreed*

*"The"*

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#### Miscellaneous

The 43 milliliter puff volume referenced in Appendix 2D is inconsistent with the 45 milliliter puff volume required by Section 660.102(B)(5) of the CMR with respect to "nicotine delivery under average smoking conditions." The Philip Morris method utilized to measure the pH of whole smoke of cigarettes used the 45 milliliter puff volume required by Section 660.102(B)(5).

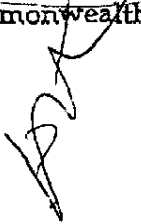
Similarly, the 43 milliliter puff volume referenced in Appendix 2E is inconsistent with the 45 milliliter puff volume required by Section 660.102(B)(5) of the CMR with respect to "nicotine delivery under average smoking conditions." Philip Morris used the 45 milliliter puff volume required by Section 660.102(B)(5) to calculate the "nicotine delivery under average smoking conditions."

#### Designated Contact

The complete name, title, business address and telephone number of the individual designated by Philip Morris as the DPH contact person for inquiries related to 105 CMR 660.000, et. seq. follows.

Dr. Jerry F. Whidby  
Technology Fellow  
Philip Morris Research & Development  
4201 Commerce Road  
Gate C/Door 17  
Richmond, Virginia  
(804) 274-5276

Dr. Whidby is familiar with the nicotine yield rating information set forth herein and will make every effort to obtain and provide, either directly, or through one of his colleagues, information related to the constituents added to each cigarette brand style and generic cigarette manufactured by Philip Morris and distributed within the Commonwealth of Massachusetts.



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Please acknowledge your receipt of the 1997 Annual Report of Philip Morris Incorporated by signing and returning one copy of this letter in the pre-addressed, postage paid mailer provided for your convenience.

Sincerely,

**Philip Morris Incorporated**

By: \_\_\_\_\_

Title: \_\_\_\_\_

**ACKNOWLEDGMENT OF RECEIPT**

**Commonwealth of Massachusetts**

By: \_\_\_\_\_

Title: \_\_\_\_\_

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